## REMARKS/ARGUMENTS

Claims 1-8 remain herein. New claims 9-131 are added hereby. Thus, claims 1-131 are pending herein.

Claims 5-8 were rejected under 35 U.S.C. §112, second paragraph. The Office Action contains a statement that claims 5-8 ". . . do not appear to further limit the claims from which they depend."

In response, it is respectfully noted that claims 1-4 each recite that the reaction product attains a detectable concentration of the target nucleic acid molecule within *at least a portion* of the sample chamber, whereas claims 5-8 each recite that the reaction product attains a detectable concentration with *the portion* of the sample chamber. Accordingly, claims 1-4 cover methods in which the entirety of the reaction product or only a portion of the reaction product attain a detectable concentration, whereas claims 5-8 each cover methods in which only a portion of the reaction product attains a detectable concentration.

Accordingly, it is respectfully submitted that claims 5-8 further limit claims 1-4, respectively, and so it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-8 were rejected over obviousness-type double patenting over claim 1 of U.S. Patent No. 6,143,496. In response, submitted herewith is a Terminal Disclaimer relative to U.S. Patent No. 6,143,496. In view of the Terminal Disclaimer, it is respectfully requested that the U.S. PTO reconsider and withdraw this rejection.

Claims 1-8 were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 5,795,748 (Cottingham '748). In addition, claims 1-8 were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 5,948,673 (Cottingham '673).

Neither Cottingham '748 nor Cottingham '673 discloses or suggests a method which comprises loading a sample portion into a sample chamber, in which if the sample portion contains at least a single molecule of a target nucleic acid, the sample portion would attain a detectable concentration of the target nucleic acid within a portion of the sample chamber after a single round of amplification.

Cottingham '748 discloses an apparatus for carrying out a homogeneous nucleic acid amplification and nucleic acid assay (Cottingham '748, Abstract). Cottingham '748 discloses an apparatus 10 which comprises a first strip 12 of sample wells 14, each of which is generally cylindrical in shape with an outside diameter of approximately 0.320 inch , an outside height of approximately 0.175 inch and a wall thickness of approximately 0.015 inch (Cottingham '748, col. 4, lines 42-43 and 59-65). Cottingham '748 further discloses forming the sample well 14 with an inside diameter of approximately 0.290 inch (Cottingham '748, col. 6, lines 45-47). Cottingham '748 discloses that Figure 5B shows the sample well assembly 22 fully assembled with a liquid biological sample 60 present in the capillary chamber 54, and that the liquid biological sample 60 substantially fills the capillary chamber 54, which has a volume of about 20 μL (Cottingham '748, col. 6, lines 50-54). Cottingham '748 discloses that the liquid biological sample is drawn into the chamber 54 by capillary forces and is spread into a thin film or disk having a height (thickness) of about 0.020 inch and a diameter of about 0.250 inch (Cottingham '748, col. 6, lines 56-60).

In a 20 μL volume, amplified product from one target molecule would not be detectable. In addition, as a result, the number of wells would not enable digital quantitation of the number of target molecules in a sample.

Cottingham '673 discloses a DNA amplification and homogeneous DNA probe assay device which includes a multiplicity of discrete sample cells in a flat "card" format, with each sample cell containing the reagents necessary for both DNA amplification and homogeneous DNA probe assay (Cottingham '673, Abstract). Cottingham '673 discloses that the size and geometry of the sample cells allows for a "hot start" of the DNA amplification reaction (Cottingham '673, col. 3, lines 35-37). Cottingham '673 discloses that the volume of the liquid biological sample will typically be about 20 μL (Cottingham '673, col. 6, lines 55-57). Cottingham '673 discloses that due to the extreme thinness of the sample chambers 24 and the large surface area of the sample chambers 24 with which the liquid biological samples 38 come into contact, the liquid biological samples 38 heat up within seconds of being pipetted into the sample cells 22 to the optimum temperature desired for DNA amplification, and that by the time the dried reagents spots 30 dissolve and diffuse throughout the liquid biological samples 38 to begin priming of the DNA amplification, the reagents are already up to the optimum temperature, thereby effecting a "hot start" of the DNA amplification reaction (Cottingham '673, col. 9, lines 4-15).

As noted above, in a 20 μL volume, amplified product from one target molecule would not be detectable and, as a result, the number of wells would not enable digital quantitation of the number of target molecules in a sample.

Accordingly, it is respectfully requested that the U.S. PTO reconsider and withdraw these rejections.

In view of the above, claims 1-131 are in condition for allowance.

If the Examiner believes that contact with Applicant's attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicant's attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

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